UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

JEFFERY CLINE,

Plaintiff, :

v.

Case No. 2:20-cv-3826
Judge Sarah D. Morrison
Magistrate Judge Kimberly A. Jolson

MEDTRONIC, INC., *et al.*, :

Defendants.

OPINION AND ORDER

This matter is before the Court on the Motion to Dismiss Plaintiff's First Amended Complaint (Mot. to Dismiss, ECF No. 11) filed by Defendants Medtronic, Inc., Medtronic USA, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Logistics, LLC (together, "Medtronic"). Plaintiff Jeffery Cline has responded to the Motion (Resp., ECF No. 18), and Medtronic has filed their reply (Reply, ECF No. 19). The Court heard oral argument on the Motion on August 24, 2021. (*See* ECF No. 28.) For the reasons set forth below, Medtronic's Motion is **GRANTED**.

I. FACTUAL BACKGROUND

All well-pled factual allegations in the First Amended Complaint (FAC, ECF No. 7) are considered as true for purposes of the Motion to Dismiss. *See Gavitt v. Born*, 835 F.3d 623, 639–40 (6th Cir. 2016). The following summary draws from the allegations in the FAC, the documents integral to and incorporated therein, and certain other documents which are subject to judicial notice. *See, e.g., Reynolds v. Medtronic, Inc.*, No. 3:20-cv-403, 2021 WL 1854968, at *4 (S.D. Ohio May 10, 2021)

(Rose, J.) (quoting *Mories v. Boston Sci. Corp.*, 494 F. Supp. 3d 461, 469 (S.D. Ohio 2020) (Marbley, J.)).

A. Medical Device Amendment to the Food Drugs and Cosmetics Act

To properly contextualize the facts of this case, the Court first adopts and excerpts the Supreme Court's summary of the regulatory regime governing medical devices:

> The Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq*., has long required FDA approval for the introduction of new drugs into the market. Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–476, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).
>
> The regulatory landscape changed in the 1960's and 1970's, as complex devices proliferated and some failed. . . .
>
> Congress stepped in with passage of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq*., which swept back some state obligations and imposed a regime of detailed federal oversight. . . .
>
> The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. [21 U.S.C.] § 360c(a)(1)(A). . . . Class II, which includes such devices as powered wheelchairs and surgical drapes . . ., is subject in addition to "special controls" such as performance standards and postmarket surveillance measures, [21 U.S.C.] § 360c(a)(1)(B).
>
> The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators . . . . In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or

"presents a potential unreasonable risk of illness or injury." [21 U.S.C.] § 360c(a)(1)(C)(ii).

[T]he MDA established a rigorous regime of premarket approval for new Class III devices . . . *Lohr*, *supra*, at 477, 116 S.Ct. 2240. A manufacturer must submit what is typically a multivolume application. . . . It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. [21 U.S.C.] § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, [21 U.S.C.] § 360e(c)(1)(G).

The FDA spends an average of 1,200 hours reviewing each application, *Lohr*, 518 U.S., at 477, 116 S.Ct. 2240, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," [21 U.S.C.] § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." [21 U.S.C.] § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. . . .

The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, [21 U.S.C.] § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, [21 U.S.C.] § 360e(d)(1)(A).

. . .

Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. [21 U.S.C.] § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. [21 U.S.C.] § 360e(d)(6); 21 CFR § 814.39(c).

> After premarket approval, the devices are subject to reporting requirements. [21 U.S.C.] § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, [21 CFR] § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. [21 U.S.C.] § 360e(e)(1); *see also* [21 U.S.C.] § 360h(e) (recall authority).

Riegel v. Medtronic, Inc., 552 U.S. 312, 315–320 (2008) (internal footnote omitted).

B. SynchroMed II Programmable Implantable Infusion Pump System

The SynchroMed II Programmable Implantable Infusion Pump System (the "SynchroMed II") is a Class III medical device approved for the intrathecal[1] infusion of drugs for severe chronic pain and spasticity. (FAC, ¶¶ 31, 34, 38.) The device consists of an infusion pump connected to a thin, flexible catheter which delivers medication directly into the spinal canal. (*Id.*, ¶ 31.) Medtronic manufactures the SynchroMed II. (*Id.*, ¶ 9.) The SynchroMed II first received pre-market approval ("PMA") on March 14, 1988. (*Id.*, ¶ 34.) Since that date, Medtronic has sought FDA approval of at least 351 supplements or changes to the originally approved device. (*Id.*, ¶ 35.)

[1] "Intrathecal drug delivery . . . uses a small pump to deliver pain medication directly to your spinal cord. The pump is surgically placed under the abdominal skin and delivers pain medication through a catheter to the area around your spinal cord." *Intrathecal Drug Delivery*, UNIVERSITY OF CALIFORNIA SAN FRANCISCO HEALTH, https://www.ucsfhealth.org/treatments/intrathecal-drug-delivery (last visited July 6, 2021).

The FAC alleges that "Medtronic knew there was a manufacturing problem with the . . . catheters and that there had been problems for years[.]" (*Id.*, ¶ 39.) Those problems were documented in both internal and FDA-issued documents. (*Id.*, ¶ 40–47, 57.)

Following regular inspections of medical device manufacturing facilities, "FDA inspectors issue FDA Form 483 documents, also known as Inspectional Observations, which list conditions or practices that indicate potential violations of statutes or regulations. The FDA may also issue a formal Warning Letter if, upon further review of the Inspectional Observations, the FDA determines that serious statutory or regulatory violations exist at" the facility. (*Id.*, ¶ 52.) The FDA inspected Medtronic facilities in Minneapolis and Puerto Rico at least six times since 2006. (*Id.*, ¶ 57.) The FDA's observations, including Medtronic's alleged failures to manufacture the SynchroMed II in accordance with FDA regulations, were recorded on Forms 483 and in Warning Letters sent to the company. (*Id.* *See also* FAC Exs. 1–7, ECF Nos. 7-1–7-7.)

The SynchroMed II has also been the subject of numerous product recalls. (*Id.*, ¶¶ 55, 91–92.) One such recall, Z-1150-2008, was initiated on January 16, 2008, posted on March 22, 2008, and terminated on June 6, 2011. (*Id.*, ¶ 112. *See also* FAC Ex. 14, ECF No. 7-14.) Recall Z-1150-2008 states:

> The company updated the labeling for the devices to include current patient management and treatment recommendations. The company received reports of inflammatory mass formations at or near the distal tip of intrathecal catheters which infuse opioids, baclofen, or chemotherapy drugs into patients. . . .

> An Urgent Medi[c]al Device Correction letter was sent January 16, 2008, to Health Care Professionals. The letter describes the incidences, symptoms and recommendations for patient management. Excerpts from the approved Medtronic Professional Labeling are also included with the letter. . . .

(FAC Ex. 14, PAGEID # 397. *See also* FAC Ex. 13, ECF No. 7-13.) The January 2008 Medical Device Correction is titled: Updated Information – Inflammatory Mass (Granuloma) At or Near the Distal Tip of Intrathecal Catheters. (FAC Ex. 13, PAGEID # 387.)

C. Mr. Cline's Complications

Mr. Cline has a history of failed back syndrome, neuritis or radiculitis due to a ruptured disc in his spine, degenerative arthritis of the spine with narrowing of the spinal canal and compression of spinal cord nerves, and chronic back and lower extremity pain. (FAC, ¶ 12.) His first SynchroMed II was implanted in October 2006. (*Id.*, ¶ 13.) The device was removed in June 2013, and replaced by a second SynchroMed II, which is the subject of this litigation (the "Device"). (*Id.*, ¶ 15. *See also* Resp., 8.)

In February 2017, Mr. Cline noticed an increase in his pain levels after a change in his medication. (*Id.*, ¶ 17.) On July 26, 2017, Mr. Cline contacted his provider stating his belief that "his pump may be broken or stalled or shut off. Mr. Cline also stated that he was scared and in pain. . . . Mr. Cline stated his back pain was so severe he couldn't stand it. He believed, at that time, that his catheter was smashed or not working and wanted the device tested for functionality." (*Id.*, ¶ 19.) His physician subsequently ordered a catheter dye study. (*Id.*, ¶ 20.) The catheter "could not be deemed perfectly functional," and Mr. Cline's physician ordered a

second dye study. (*Id.*, ¶ 21.) That summer, Mr. Cline began relying on oral medications to control his pain. (*Id.*)

On June 19, 2018, a nurse practitioner reviewed an MRI taken the previous month and "believed there was a possible arachnoid cyst spanning the L1–3 space of [Mr. Cline's] spine. This is the same location where Mr. Cline's catheter was noted to have been" in a previous MRI. (*Id.*, ¶ 24.) The cyst was diagnosed as a granuloma. (*Id.*, ¶ 25–26.) Mr. Cline was seen the following month regarding the granuloma and extreme pain in his back and lower extremities. (*Id.*, ¶ 26.) His nurse noted that Mr. Cline still required oral pain medications, in addition to his intrathecal dose. (*Id.*) As of the date of filing, the Device remained implanted in Mr. Cline's abdomen along with the granuloma. (*Id.*, ¶ 27.)

II. PROCEDURAL BACKGROUND

Mr. Cline commenced this action on July 30, 2020. (ECF No. 1.) The FAC was filed in response to Medtronic's first motion to dismiss. The FAC asserts claims for: strict liability manufacturing defect, under Ohio Rev. Code § 2307.74 (Count I); strict liability inadequate warning or instruction, under Ohio Rev. Code § 2307.76 (Count II); breach of implied warranty of merchantability, under Ohio Rev. Code §§ 1302.27, 1302.28 (U.C.C. §§ 2-314, 2-315) (Count III); and punitive damages, under Ohio Rev. Code § 2315.21(C)(1) (Count IV).[2] Medtronic now seeks dismissal of the FAC for failure to state a claim upon which relief may be granted.

[2] The FAC also includes a claim for negligent manufacturing defect under Ohio Rev. Code § 2307.74. Mr. Cline later withdrew this claim. (Resp., 16.)

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a) requires a plaintiff to plead each claim with sufficient specificity to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotations omitted). A complaint which falls short of the Rule 8(a) standard may be dismissed if it fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). The Supreme Court has explained:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal citations and quotations omitted). The complaint need not contain detailed factual allegations, but it must include more than labels, conclusions, and formulaic recitations of the elements of a cause of action. *Directv, Inc. v. Treesh*, 487 F.3d, 471, 476 (6th Cir. 2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

IV. ANALYSIS

In its Motion to Dismiss, Medtronic argues that Mr. Cline's claims are barred by Ohio's two-year statute of limitations and are either expressly or impliedly pre-

empted by federal law. Medtronic further challenges the sufficiency of the factual allegations presented in the FAC. Medtronic's arguments are well-taken and, together, warrant dismissal of each claim asserted in the FAC.

A. Statute of Limitations

Medtronic first argues that Ohio's two-year statute of limitations bars Mr. Cline's claims.[3] A motion to dismiss for failure to state a claim "can be an appropriate mechanism for dismissal of time-barred claims . . . ['] when the complaint shows conclusively on its face that the action is indeed time-barred.'" *Hawkins v. CooperSurgical, Inc.*, No. 1:19-cv-01047, 2020 WL 1864907, at *2 (S.D. Ohio Apr. 14, 2020) (Barrett, J.) (quoting *Allen v. Andersen Windows, Inc.*, 913 F. Supp. 2d 490, 500 (S.D. Ohio 2012) (Frost, J.)). Ohio law provides that "an action based on a product liability claim and an action for bodily injury . . . shall be brought within two years after the cause of action accrues." Ohio Rev. Code § 2305.10(A). A cause of action for bodily injury caused by exposure to a medical device

> accrues upon the date on which the plaintiff is informed by competent medical authority that the plaintiff has an injury that is related to the exposure, or upon the date on which by the exercise of reasonable diligence the plaintiff should have known that the plaintiff has an injury that is related to the exposure, whichever date occurs first.

Ohio Rev. Code § 2305.10(B)(1). This is commonly known as the "discovery" rule. *See Hawkins*, 2020 WL 1864907, at *3 (noting that, in a "medical device case," "the

[3] "In diversity cases[,] the law of the State in which a federal court sits must be followed with respect to the statute of limitations[.]" *Atkins v. Schmutz Mtg. Co.*, 372 F.2d 762, 764 (6th Cir. 1967).

'discovery' rule applies, and the statute of limitations accrues when a plaintiff knows or reasonably should have known that her injury was caused by the defendant"). In response to the COVID-19 pandemic, the Ohio General Assembly tolled all limitations periods set to expire between March 9, 2020, and July 30, 2020, such that those limitations periods expired on July 30, 2020. H.B. 197, 133d Gen. Assemb., § 22 (Ohio 2020).

Mr. Cline filed this action on July 30, 2020. (ECF No. 1.) He argues that the statute of limitations on his claims began to run in June 2018—when his granuloma was diagnosed—and that his claims were thus timely filed under Ohio Rev. Code § 2305.10 and H.B. 197. Medtronic concedes that this action was initiated within two years after the granuloma was diagnosed (plus the extension under H.B. 197), but argues that the limitations period in fact began to run in July 2017, when Mr. Cline first "suspected his device was not functioning properly." (Reply, 1.) Neither party is entirely correct.

The FAC alleges that Mr. Cline suffered two distinct injuries caused by his Device. First, it alleges that the Device's "catheter occluded and/or disconnected from [the] pump, which resulted in a cycle of overinfusion of pain medication due to leakage followed by underinfusion due to an inadequate supply of remaining medication." (FAC, ¶ 88.) In support, Mr. Cline alleges:

> On or about July 26, 2017, Mr. Cline contacted OSU stating that Mr. Cline believed his pump may be broken or stalled or shut off. Mr. Cline also stated that he was scared and in pain. When a registered nurse returned his call, Mr. Cline stated his back pain was so severe he couldn't stand it. He believed, at that time, that his catheter was smashed or not working and wanted the device tested for functionality.

> . . . .
>
> As of September 11, 2017, records indicate that Mr. Cline had resorted to taking oral medications, including Methadone and Oxycodone, to control the pain in his spine and legs. On or about this date, records also indicate that Dr. Severyn planned to perform a catheter dye study in four weeks because the second catheter could not be deemed perfectly functional and may need to be replaced.

(*Id.*, ¶¶ 19, 21.)

The FAC also alleges that the Device "caused the formation of a granuloma around the area where the second catheter was placed." (*Id.*, ¶ 121.) The factual allegations supporting this theory reflect:

> In or about May 2018, Mr. Cline received an MRI at a separate facility with dye contrast which was then sent to OSU.
>
> On or about June 19, 2018, nurse practitioner Christina D. McGhee noted that she reviewed the report of Mr. Cline's MRI and believed there was a possible arachnoid cyst spanning the L1–3 space of his spine. This is the same location where Mr. Cline's catheter was noted to have been on September 22, 2016, the date of Mr. Cline's previous MRI. . . .
>
> On or about June 26, 2018, Ms. McGhee noted that she, and Mr. Cline's other doctors, suspected a granuloma had formed in the space along the L1–3 of Mr. Cline's spine.
>
> On or about July 31, 2018, Mr. Cline was seen at OSU regarding the granuloma which formed around the area of his second catheter and for extreme lower back and lower extremity pain. . . .

(*Id.*, ¶¶ 23–26.)

The FAC does not allege any connection between the Device's failure to administer Mr. Cline's medication as programmed and the subsequent granuloma. The Court declines to infer any such connection.

Even taking as true all allegations in the FAC, Mr. Cline's claims are time-barred to the extent they are based on the Device's failure to administer medication

as programmed. Mr. Cline knew or should have known about any such malfunction in 2017. That summer, Mr. Cline's pain increased to levels so severe he required a prescription for oral medications to control it. He also underwent two dye studies to test the functionality of the Device's catheter—the second was required only because the first revealed that the "catheter could not be deemed perfectly functional and may need to be replaced." (*Id.*, ¶ 21.) At that point in time, Mr. Cline either knew or should have known that his alleged injury was caused by the Device. The statute of limitations on Mr. Cline's claims to recover for such injury expired before H.B. 197's tolling period began. Accordingly, Medtronic's motion to dismiss Mr. Cline's claims as time-barred is **GRANTED** to the extent the claims are based on the Device's failure to deliver medication as programmed, but **DENIED** to the extent the claims are based on Mr. Cline's granuloma.

B. Express Pre-Emption and Sufficiency of the Pleadings

Medtronic next argues that Mr. Cline's claims (brought under state law) are expressly pre-empted by federal law. The MDA includes an express pre-emption clause, precluding a state from imposing any requirements (i) that are different from or in addition to those imposed by the FDCA, and (ii) that relate to the safety or efficacy of the device. 21 U.S.C. § 360k(a). The Supreme Court has established a two-step inquiry to determine whether a claim is pre-empted:

> The analysis asks: (1) whether the [f]ederal [g]overnment has established requirements applicable to the device; and (2) whether the asserted . . . claims impose any state requirements regarding safety and effectiveness that are different from or in addition to those under the MDA.

White v. Stryker Corp., 818 F. Supp. 2d 1032, 1036 (W.D. Ky. 2011) (citing *Riegel* 552 U.S. at 321–22). "While '[t]he Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties,' it does not preempt all state law claims concerning medical devices." *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 985 (N.D. Ohio 2017) (quoting *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439 (6th Cir. 2010)). What remains is a "narrow gap" which allows parallel claims—"state law claims premised on a violation of FDA regulations[—]to avoid express preemption." *Id.* (citing *Riegel*, 552 U.S. at 321) (citation corrected).

In this case, the first step—whether the federal government has established requirements applicable to the Device—is easily satisfied. "All PMA-approved medical devices, including Class III medical devices, automatically fulfill this first step." *Mories v*, 494 F. Supp. 3d at 468 (citing *Riegel*, 552 U.S. at 332.) The second step requires further analysis, performed count-by-count.

Medtronic challenges the sufficiency of the pleadings only after arguing that Mr. Cline's claims are pre-empted. However, "because preemption under the FDCA derives from the Supremacy Clause of the United States Constitution, courts should 'first analyze whether each claim can stand under state law, and only then decide the preemption questions when necessary.'" *Smith v. ZOLL Med. Corp.*, No. 1:20-cv-2204-STA-jay, 2020 WL 7233366, at *5 (W.D. Tenn. Dec. 8, 2020) (quoting *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1328 (11th Cir. 2017)) (alteration omitted). *See also Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 832 (W.D. Ky. 2014)

(finding first "that Plaintiffs' claims pass muster under Rule 8" before determining whether they are pre-empted by federal law).

The Court will undertake these analyses together.

1. Count I – Strict Liability Manufacturing Defect

Count I of the FAC asserts a manufacturing defect claim. To succeed on a manufacturing defect claim, a plaintiff must show that (i) the manufacturer's product was defective in manufacture or construction, (ii) a defective aspect of that product proximately caused the harm complained of, and (iii) the manufacturer manufactured or constructed the actual product that was the cause of the harm. Ohio Rev. Code § 2307.73. A manufacturer's product is defective in manufacture or construction if:

> when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code § 2307.74. Medtronic argues that the FAC "asserts only conclusory allegations about unidentified defects in Plaintiff's [Device], untethered to his injuries." (Mot. to Dismiss, PAGEID # 472.) Said another way, Medtronic's position is that the FAC fails to establish the first or second elements of the claim. As to the second element, the Court agrees.

Mr. Cline must first allege that the Device was defective in manufacture or construction—in other words, that it "deviated in a material way" from the design

specifications. Mr. Cline attempts to satisfy this element by alleging that Medtronic violated various federal regulations.

Even assuming the first element is sufficiently pled, the FAC fails to allege that a defective aspect of Mr. Cline's Device proximately caused his injuries. Nothing in the FAC connects the formation of a granuloma to a defect in Mr. Cline's Device, except his *ipse dixit*. The FAC certainly alleges that Medtronic violated a vast number and variety of FDA regulations, to the serious potential detriment of patients. But the only regulations allegedly violated that pertain to granuloma are reporting requirements.[4] (*See* FAC, ¶¶ 68a (failure to report adverse events), 70 (failure to report correction).) The Court has no basis to infer that a violation of reporting requirements applicable to a product can constitute a material deviation of that product from it design specifications. Accordingly, the allegations do not show that Mr. Cline's injuries were proximately caused by a defective aspect of his Device. Count I of the FAC fails to state a claim upon which relief may be granted.

[4] The 2006 Warning Letter identified deficiencies related to the catheter tip bonding and bonding process. (FAC, ¶¶ 58–62; FAC Ex. 1, ECF No. 7-1.) The 2007 Warning Letter identified deficiencies in Medtronic's complaint handling procedures, including failure to report instances of granuloma to the FDA and failure to report a correction conducted to reduce the risk of inflammatory mass occluding intrathecal catheters. (FAC, ¶¶ 63–72; FAC Ex. 2, ECF No. 7-2.) The 2009 Warning Letter identified deficiencies related to manufacture of the pump, including pumps manufactured without propellant, without a perforated septum, without a safety mechanism to ensure the pump is not overfilled, and without having been sterilized. (FAC, ¶¶ 73–77; FAC Ex. 4, ECF No. 7-4.) The 2012 Warning Letter identified deficiencies related to the pump's motor stalling due to corrosion and complaint handling procedures. (FAC, ¶¶ 78–83; FAC Ex. 6, ECF No. 7-6.) The 2013 Inspection revealed deficiencies related to catheter occlusion and corrective and preventive action procedures. (FAC, ¶¶ 84–85; FAC Ex. 7, ECF No. 7-7.)

Mr. Cline argues in favor of the opposite conclusion, stating that "[b]ecause Medtronic produced a device which did not adhere to the FDA's approved design, condition, and specifications, Medtronic deviated from the device's PMA requirements in violation of [ ] Federal law . . . ." (Resp., 16.) Mr. Cline relies on his pleadings and declines to identify that deviation, or clarify its nature, in his Response. However, it is not sufficient to "simply incant the magic words, 'Medtronic violated FDA regulations[.]'" *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). Without identifying violations that could, by reasonable inference, proximately cause the injuries complained of, the FAC effectively offers no "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. At oral argument, Mr. Cline encouraged the Court to allow discovery into the manufacture of his Device before dismissing his claims. But this Court has noted that that Sixth Circuit does not excuse pleading deficiencies "even if [the operative] facts are only within the head or hands of the defendants." *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) (Black, J.) (quoting *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011)).

Because Count I fails to satisfy the pleading standard of Rule 8, the Court need not and does not address whether the claim is pre-empted.

Medtronic's motion to dismiss Count I is **GRANTED**.

2. Count II – Strict Liability Inadequate Warning or Instruction

Count II of the FAC asserts an inadequate warning or instruction claim. Under Ohio law, a product is defective due to inadequate warning or instruction if:

> [t]he manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and] [t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76. Medtronic argues that Count II must fail because it is expressly pre-empted. The Court agrees.

To avoid pre-emption, "an action based on a state law [must] mirror federal requirements [and must not] impose[] requirements exceeding the MDA statutory ceiling." *Mories*, 494 F. Supp. 3d at 471. Further, "[a] plaintiff must bolster her legal claims with factual evidence about how the medical device at issue violated the federal regulation." *Id.* (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)).

Count II fails to state a parallel claim. As adapted from this Court's analysis of a near-verbatim complaint[5] filed by Mr. Cline's counsel in a different action:

> [I]n the context of this inadequate warning claim, [Mr. Cline's] allegations do not meet the requirement that [he] "identify state law that parallels federal regulations" or requirements that Medtronic allegedly violated. *Mories*, 494 F. Supp. 3d at 471; *see also Aaron*, 209 F. Supp. 3d at 1005 ("the federal duty to report certain information to the

[5] *Compare* FAC, *with Reynolds v. Medtronic, Inc.*, No. 3:20-cv-403, ECF No. 12 (S.D. Ohio filed Sept. 29, 2020).

> FDA is not identical, and thus not parallel, to the state-law duty to provide warnings to patients or their physicians") (emphasis, internal citation, and internal quotation marks omitted). Additionally, allegations indicate that this claim is based on state requirements that are "different from, or in addition to" the federal requirements applicable to the device. 21 U.S.C. § 360k(a); *Aaron*, 209 F. Supp. 3d at 1005 ("to the extent that Plaintiffs allege that Defendants were required to give any warning other than those that were required by the FDA as part of its PMA of the device, those claims are expressly denied as being inconsistent with federal law"); *Riegel*, 552 U.S. at 329, 128 S.Ct. 999 (the preemption provision surely "would pre-empt a jury determination that the FDA-approved labeling for a device violated a state common-law requirement for additional warnings"). For example, paragraph [150] alleges that "Medtronic failed to provide additional warning or instruction equal to the seriousness of the harm under which this claim is brought." ([FAC] at PageID [# 308]; *see also id.* at PageID [#309] ("Plaintiff claims that [his] particular SynchoMed II device was defective for failure to provide adequate warnings because [his] individual device was defective.").) As pleaded in the [FAC], the claim is preempted because it does not fall within the "narrow gap" for avoiding express preemption in accordance with *Riegel*'s two-part test.
>
> Finally, [Mr. Cline] says that the Motion "should be dismissed to allow [him] time to conduct discovery." ([Resp.,] at [18].) However, a plaintiff's "claims must meet the pleading standards of Rule 8 as defined in *Iqbal* and *Twombly* in order to survive a motion to dismiss." *Aaron*, 209 F. Supp. 3d at 1001; *see also Becker v. Smith & Nephew, Inc.*, Civ. No. 15-2538, [2015 WL 4647982], at *3 (D.N.J. Aug. 5, 2015) ("plaintiffs contend that they should be permitted to allege unspecified deviations from FDA requirements at the pleading stage, and fill in the blanks through discovery . . . but a plaintiff must successfully plead a claim before obtaining discovery, not the other way around"). In the context of medical device claims, courts have found that, based on the plaintiff's own medical records and access to the FDA's website, the "plaintiff could have, with reasonable effort, described the federal requirements that have allegedly been violated and any parallel state statute." *Warstler*, 238 F. Supp. 3d at 985 n.3 (internal quotation marks omitted).

Reynolds v. Medtronic, Inc., No. 3:20-cv-403, 2021 WL 1854968, at *10 (S.D. Ohio May 10, 2021) (Rose, J.) (footnotes and original alterations omitted).

> Medtronic's motion to dismiss Count II is **GRANTED**.

3. Count III – Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose

Count III asserts that Medtronic violated the implied warranties of merchantability and fitness for a particular purpose. Under Ohio law, a warranty of merchantability is implied in every contract for the sale of goods, unless excluded. Ohio Rev. Code § 1302.27. *See also* U.C.C. § 2-314. To be merchantable, goods must, *inter alia*, be "of fair average quality," be "fit for the ordinary purposes for which such goods are used, and "run . . . of even kind, quality and quantity, within each unit and among all units involved[.]" Ohio Rev. Code § 1302.27(B). A warranty of fitness for a particular purpose is similarly implied where "the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods[.]" Ohio Rev. Code § 1302.28. *See also* U.C.C. § 2-315.

Just as in *Reynolds*, "Count [III] suffers from the same failure as Count [II]." *Reynolds*, 2021 WL 1854968, at *11. "[C]ourts have consistently found that state law claims for breach of warranties based on the safety or effectiveness of a PMA device, impose requirements that are different from, or in addition to federal regulations, and thus are preempted." *Warstler*, 238 F. Supp. 3d 978, 990 (N.D. Ohio 2017) (cleaned up) (internal quotation and citation omitted). For Mr. Cline to be successful on Count III "would effectively require [a finding] that [a PMA device must] be safer or more effective than demanded by the FDA." *Id.* (quoting *Aaron*, 209 F. Supp. 3d at 1008). Accordingly, Medtronic's motion to dismiss Count III is **GRANTED**.

4. Count IV – Punitive Damages

Finally, Count IV seeks punitive damages on the grounds that "[t]he actions or omissions of th[e] defendant demonstrate malice or aggravated or egregious fraud[.]" Ohio Rev. Code § 2315.21(C)(1). A claim for punitive damages is "derivative in nature." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514–15 (6th Cir. 2003). "A derivative cause of action may not provide greater relief than that available under the primary cause of action." *Id.*, 350 F.3d at 515 (citation omitted). Because Counts I–III have been dismissed, the Court must also dismiss Count IV.

Medtronic's motion to dismiss Count IV is **GRANTED**.

C. Implied Pre-Emption

Because the Court has concluded that Count I–IV are properly dismissed on other grounds, the Court need not and does not analyze Medtronic's alternative argument that they are impliedly pre-empted.

V. CONCLUSION

Medtronic's Motion to Dismiss the First Amended Complaint (ECF No. 11) is **GRANTED**. Mr. Cline's First Amended Complaint (ECF No. 7) is **DISMISSED**. The Clerk is **ORDERED** to **TERMINATE** this case from the docket of the United States District Court for the Southern District of Ohio.

IT IS SO ORDERED.

/s/ Sarah D. Morrison
SARAH D. MORRISON
UNITED STATES DISTRICT JUDGE